No. 80-563

Supreme Court, U. S.
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IN THE

Supreme Court of the United States

October Term, 1980

PREMO PHARMACEUTICAL LABORATORIES, INC., FEDERAL PHARMACAL, INC., SEYMOUR N. BLACKMAN, STEVEN BLACKMAN and JOHN BLACKMAN,

Petitioners,

v.

ELI LILLY AND COMPANY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY BRIEF

Petitioners Premo Pharmaceutical Laboratories, Inc., Federal Pharmacal, Inc., Seymour N. Blackman, Steven Blackman and John Blackman submit this brief in support of their Petition for a Writ of Certiorari, which seeks review of the decision of the United States Court of Appeals for the Third Circuit in this case, and to reply to arguments raised by respondent in its Brief in Opposition to the Petition for a Writ of Certiorari.

Argument

In its Brief in Opposition to the Petition for a Writ of Certiorari, respondent does not dispute the substantive arguments raised in the Petition to the effect that the lower courts incorrectly interpreted the Patent Statutes and judicial precedents in reaching their decisions holding that a sufficient showing had been made by respondent to warrant the granting of a preliminary injunction. Instead, respondent argues only that:

(1) none of the "technical" questions of patent law which petitioners have asked this Court to review were decided by the Courts below because those Courts were ruling only on a motion for preliminary injunction and as such did not rule on the merits of the substantive arguments; and

(2) the only question that may properly be presented for review by this Court is whether the District Court abused its discretion in granting the preliminary injunction.

Respondent goes on to contend that the District Court "acted well within the bounds of its discretion in granting the preliminary injunction" (Brief in Opposition, p. 4) but, in any case, the question of whether the District Court abused its discretion "does not present important questions of federal law" (*id.*). Finally, respondent claims that petitioners will have ample opportunity at the trial phase of this case to advance their legal arguments to the lower courts and that the legal questions raised in the Petition for a Writ of Certiorari are not ripe for decision at this point.

Respondent's characterizations of the questions raised for review in the Petition, of the nature of the decision

below, and of the present posture of this case are highly erroneous.

A perusal of the Opinion of the Third Circuit Court of Appeals which petitioners seek to have reviewed will demonstrate unequivocally that the Court conclusively ruled on the merits of the important questions of patent law discussed in the Petition for Certiorari. The questions raised by petitioners and citations to the Third Circuit Opinion where those questions were decided are as follows:

1. Whether a patent claim reciting a structurally obvious chemical compound can be held valid under 35 U.S.C. §103 solely because the compound possesses an unexpected property not recited in the claim.

> "We too are persuaded that, in determining whether a new drug meets the nonobviousness requirement of §103, the district courts should consider all of the properties of the drug—including its structure, uses, and other traits—and compare those properties with their counterparts in the prior art. If the new compound, although structurally obvious, exhibits uses or traits that, at the time of their discovery, were not predictable to chemists or other persons skilled in the prior art, such differences indicate that the new compound is nonobvious for the purposes of §103. . . . If the unexpected property results in a substantial improvement over the prior art in respect to the therapeutic effectiveness or usefulness of the drug, however, it would appear to contravene the purposes of the patent laws to deny patentability on the basis of obviousness." (21a-22a;* footnotes omitted).

> "There is no claim that this type of modification was not obvious to other chemists working in the field at that time, or that the procedure was a difficult one. Thus, the structural composition of the cephalexin

* Page numbers in the form "—a" refer to pages in the Appendices to the Petition for Certiorari.

molecule might well be termed obvious in light of the prior art."

* * *

"Cephalexin did exhibit, however, the totally unexpected trait of one hundred percent absorption which made it the orally effective cephalosporin for which the chemists had been searching. This unexpected property therefore represented a substantial advancement over the prior art." (22a-23a)

"The manner of producing cephalexin was readily predictable and performable, and therefore concededly obvious. But the real advancement over the prior art —cephalexin's one hundred percent absorption rate— was totally unexpected, even by the chemists who proposed its synthesis. Hence, taking cephalexin as a whole, we conclude that it was a nonobvious advancement over the prior art." (24a-25a)

"Accordingly, we join our sister courts of appeals in holding that, in cases involving the patentability of chemical compounds, the determination of obviousness under §103 should be based on a comparison of the structures of all properties possessed by the new compound and the prior art, including their respective structures, uses, and pharmacological traits." (25a)

2. Whether a patent claim reciting a chemical compound as described in Question 1 can be valid under 35 U.S.C. §§103 and 112 where the unexpected property possessed by the compound and relied on to save the claim from invalidity because of structural obviousness was neither disclosed in the specification and claims of the original application nor even known at the time the application was filed.

"Hence, although the application did not expressly identify the nonobvious trait—the one hundred percent rate of absorption—the information Eli Lilly did supply was such that the nature of the trait could

readily be identified by a person skilled in the prior art. Under these circumstances, the nonobvious trait may be said 'to flow inherently' from the properties and data supplied in the application and accompanying documents. Therefore, we conclude that Eli Lilly adequately complied with the disclosure requirements of §112." (28a)

3. Whether a patent claim reciting a compound as described in Question 1 can be held valid under 35 U.S.C. §103 where the alleged disclosure of the unexpected property relied on to save the claim from invalidity because of structural obviousness constituted new matter in violation of 35 U.S.C. §132 which was added to the patent application several years after filing thereof.

"Inasmuch as a chemical compound and its properties 'are one and the same thing,' newly discovered properties of the compound not disclosed in the original specification or abstract may be added by amendment without being treated as 'new matter' under §132. Moreover, as in *Triax*, the decision of the Patent Office to admit the material contained in the amendment, which indicates that it did not consider the amendment to be 'new matter,' should be accorded substantial weight. Under these circumstances, we are not persuaded that the information contained in the 1968 amendment constituted 'new matter' in violation of §132." (30a; footnotes omitted).

4. Whether a patent claim reciting a compound as described in Question 1 can be held valid under 35 U.S.C. §§103 and 112 where the alleged disclosure of the unexpected property relied on to save the claim from invalidity because of structural obviousness describes equally well the very prior art compound in view of which the patented compound was held to be structurally obvious.

The Court of Appeals implicitly decided this question in its discussion of the sufficiency of the disclosure of cephalexin's 100-percent gut absorbability (26a-28a). The Court had found that cephaloglycin was considered a satisfactory oral antibiotic and was marketed for oral administration prior to the advent of cephalexin (6a-7a). Yet, the Third Circuit ruled that the disclosure in the abstract of the suit patent which applies equally well to cephaloglycin and cephalexin was adequate to disclose the unexpected pharmacological property possessed by the latter drug (28a; *see* Petition for Certiorari at pp. 6-7, 10-11, 24).

5. Whether a patent claim reciting a compound as described in Question 1 can be held valid under 35 U.S.C. §§101, 102(f), 111 and 116 where the unexpected property relied on to save the claim from invalidity because of structural obviousness was discovered by someone other than the named inventors several years after the alleged discovery of the claimed chemical compound by said named inventors.

> "Although we have held today that, in assessing the obviousness of a new drug under §103, courts must consider all of the properties of the new compound, the fact that a person other than Dr. Morin or Dr. Jackson *discovered* the nonobvious trait possessed by cephalexin does not make that person an *inventor* of cephalexin for purposes of §116. . . . In the words of §116, cephalexin was 'made by' the two named inventors, not by the biochemists who first noted that the organic chemists' predictions had been realized." (33a)

Although the decision of the Third Circuit in this case was technically one affirming the granting of a preliminary injunction rather than a decision on the merits, that Court has clearly ruled on all of petitioners' substantive argu-

ments.[1] Petitioners are thus foreclosed from advancing these same arguments against the validity of the suit patent at trial unless this Court reverses the Third Circuit decision which is based on erroneous interpretations of the law and improper statutory construction.

Respondent's argument that the lower courts could not reach the merits of petitioners' legal contentions on a motion for preliminary injunction and that the only question presented for review by this Court is whether the lower courts abused their discretion is fallacious. In the first place, as has been demonstrated, the Third Circuit has ruled on the merits of petitioners' arguments against the validity of the suit patent. In the second place, one of the traditional requirements for granting a preliminary injunction is that the moving party has shown a likelihood of success on the merits at trial and an appellate court must examine the merits of the case and the legal arguments advanced by the parties in order to determine whether the preliminary injunction was properly granted or denied by the lower court. *See, e.g., Delaware & Hudson Railway Co.* v. *United Transportation Union,* 450 F.2d 603, 619-20 (D.C. Cir. 1971), *cert. denied,* 403 U.S. 911 (1971). Moreover, as the Second Circuit Court of Appeals stated with respect to the argument that it could only review a district court's decision on a preliminary injunction motion by applying the abuse of discretion standard:

> "Congress would scarcely have made orders granting or refusing temporary injunctions an exception to the general requirement of finality as a condition to appealability, 28 U.S.C. §1292(a)(1), if it intended appellate courts to be mere rubber-stamps save for the rare

1. It should also be noted that the District Court held a hearing in connection with the motion for preliminary injunction which was termed "extensive" by the Third Circuit (4a) and at that hearing the parties put in substantial evidence, including expert testimony.

> cases when a district judge has misunderstood the law or transcended the bounds of reason."

Omega Importing Corp. v. *Petri-Kine Camera Co.*, 451 F.2d 1190, 1197 (2d Cir. 1971); *see also, Buffalo Courier-Express, Inc.* v. *Buffalo Evening News, Inc.*, 601 F.2d 48, 59 (2d Cir. 1979).[2]

Even though the decision on a preliminary injunction motion is traditionally viewed as being within the discretion of the district judge, "[a] judge's discretion is not boundless and must be exercised within the applicable rules of law or equity." *Blackwelder Furniture Co. of Statesville, Inc.* v. *Seilig Mfg. Co.*, 550 F.2d 189, 193 (4th Cir. 1977). An appellate court's review of a lower court's application of the law in connection with a preliminary injunction motion is not limited by the "clearly erroneous" standard which restricts review of findings of fact under Rule 52(a) F.R.Civ.P. *Id.; Sea-Land Service, Inc.* v. *Kreps*, 566 F.2d 763, 773 (D.C. Cir. 1977); *see Delaware & Hudson Railway Co.* v. *United Transportation Union, supra*, at 620.

In granting a preliminary injunction on behalf of respondent in this case, the District Court reached the merits of petitioners' attack on the validity of the patent (63a-71a), and in affirming that decision, the Court of Appeals set forth its view of the applicable law in no uncertain terms. In a similar situation, the Court of Appeals for the District of Columbia Circuit has stated:

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2. The cases cited in this Brief are all circuit court cases dealing with the scope of reviewability of a district court decision on preliminary injunction. It is submitted, however, that the reasoning of these courts is equally applicable to the scope of review on appeal to this Court of a circuit court's decision affirming the granting of a preliminary injunction by a district court. Moreover, respondent has cited circuit court cases in its Brief in Opposition in support of its contention that the scope of review in this case should be severely restricted (Brief in Opposition at p. 3, footnote 2).

> "Insofar as the action of the trial judge on a request for preliminary injunction rests on a premise as to the pertinent rule of law, *that premise is reviewable fully and de novo in the appellate court.* The matter stands in a different posture from that involved when there is no question or disagreement as to the legal principle involved, and the element of probability of success on the merits depends on a forecast as to the shape of the facts likely to emerge at trial. If the appellate court has a view as to the applicable legal principle that is different from that premised by the trial judge, it has a duty to apply the principle which it believes proper and sound. The reversal of the trial judge in no way reflects a determination that he was unreasonable or arbitrary, or chargeable with an abuse of discretion, but only and simply that his premise as to the applicable rule of law is deemed erroneous by the appellate court."

Delaware & Hudson Railway Co. v. *United Transportation Union, supra,* at 620-21 (emphasis added).

Petitioners have shown in the Petition for Certiorari that the Court of Appeals rejected petitioners' arguments because it adopted an incorrect view of the law with respect to the patentability of chemical compounds and other issues central to patent law. Furthermore, the questions raised in the Petition are ripe for review by this Court—if the Third Circuit's erroneous conclusions of law are not corrected by this Court, any further proceedings in this case, including a trial on the merits, would be little more than a futile exercise on the part of petitioners.

Even more significantly, if the Third Circuit's approach to the patentability of pharmaceutical compounds is not corrected by this Court, it may well be followed by other Courts of Appeal, resulting in a serious dilution of the constitutional and legislative requirements for patentable

invention and complete disclosure. Since a very large number of new pharmaceutical compounds are chemically obvious at the time of their development, upholding (as the lower courts have done) the validity of patents on these obvious substances because of allegedly unexpected properties discovered years after the patent applications were filed by persons other than those who are named as inventors in the patents, and which properties are not even described in the patents, will serve to expand the scope of the monopolies acquired by the giant drug companies and restrict competition in the industry. This lessening of competition and the resulting excessive prices for the drugs protected by patents that are statutorily invalid will be seriously detrimental to the public welfare. And although it is in the public interest to encourage the development of new pharmaceutical agents, sustaining the validity of improperly acquired patent monopolies is surely a dangerous vehicle for creating incentives to such development.

Conclusion

It is respectfully submitted by petitioners that a Writ of Certiorari should be issued to review the judgment of the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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